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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,804	08/16/2001	Carla M. Mann	AB-047U2	3341
23845	7590	01/13/2004		
ADVANCED BIONICS CORPORATION 12740 SAN FERNANDO ROAD SYLMAR, CA 91342				
			EXAMINER SCHAETZLE, KENNEDY	
			ART UNIT 3762	PAPER NUMBER
			DATE MAILED: 01/13/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,804

Applicant(s)

MANN ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-19,21-30 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-38 is/are allowed.
- 6) ☒ Claim(s) 1,4 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the species wherein the electrodes and/or catheter discharge portion is implanted with a perineal approach (claims 4 and 31-38) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Although the applicant did not elect claims 1 and 20, the applicant is entitled to their consideration since the examiner had considered said claims to be generic in the previous Office Action. In the interests of expediency, the examiner will consider claims 1 and 20 along with elected claims 4 and 31-38.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lue et al. (Pat. No. 4,585,005).

Lue et al. disclose a method for stimulating at least one tissue affecting specific anatomical structures of the perineum comprising a stimulator 12 that generates a stimulation pulse in accordance with prescribed stimulation parameters, a lead 13 connected to the stimulator including at least two electrodes (note col. 6, lines 8-13) for delivering the stimulation and implanted adjacent to at least one tissue of the perineum to be stimulated (note col. 6, lines 56-66 and Figs. 1-4). The stimulator 12 is implanted at a location remote from the stimulated tissue, and the lead is subcutaneously tunneled to the stimulator location (see col. 7, lines 15-18).

Regarding claim 4, note again col. 6, lines 56-66.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 20 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lue et al. (Pat. No. 4,585,005).

Regarding the rejection of claim 20 under 35 U.S.C. 102(b), comments related to those given above in the rejection of claim 1 apply here as well. Although Lue et al. do not explicitly refer to means for implanting the stimulator, it is axiomatic that some surgical instrument (such as for example a scalpel) must have been used in order to gain access to the body. To use a cutting tool as a means to gain access to the body in order to surgically implant the stimulator 12 would have therefore been considered blatantly obvious by those of ordinary skill in the surgical arts. Likewise, Lue et al. do not explicitly refer to a means for subcutaneously tunneling the lead to the stimulator site. Again, it would have been axiomatic to use some form of tool (e.g., forceps, guide catheter, etc.) to assist in tunneling the lead through tissue to the appropriate site in any surgical procedure in order to accurately place the lead.

Allowable Subject Matter

6. Claims 31-38 are allowed.

There does not appear to be a teaching in the prior art of record for providing a method of treating patients with incontinence, urgency, frequency, and/or pelvic pain comprising the steps of perineally or vaginally implanting at least two electrodes adjacent tissue to be stimulated, and tunneling the lead to a remotely located implanted stimulator. The method disclosed by Lue et al. concerns erectile dysfunction.

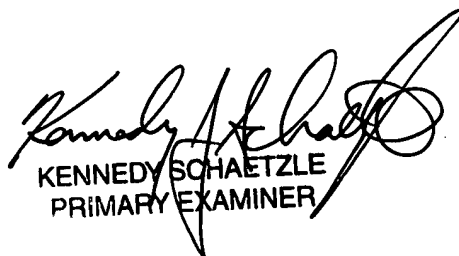
Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
January 11, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER